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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,591	10/03/2000	Steven C. Quay	20424-000510US	5933

7590 06/17/2002

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EXAMINER

JONES, DWAYNE C

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/17/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/678,591

Applicant(s)

QUAY, STEVEN C.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g. 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1-50 are pending
2. Claims 1-50 are rejected.

Response to Arguments

3. Applicant's arguments with respect to claims 1-50 have been considered but are moot in view of the new ground(s) of rejection. The rejection of claims 1-12 and 26-38 under 35 U.S.C. 112, first paragraph, is again maintained because there is no support or guidance in the instant specification for the prevention of cancer.
4. In the Office Action of December 18, 2001, the rejection of these claims, as to not providing an enabling disclosure for the prevention or prophylaxis of breast cancer is maintained and did address *In re Wands*, 8USPQ 2d 1400 (Fed. Cir. 1988). This rejection discussed factors of enablement as cited in *Wands*, specifically that the cancer art is highly unpredictable, the state of the art with the Stein reference, the lack of guidance and/or working examples demonstrating the prevention of cancer, especially in humans. Accordingly, this rejection is maintained for both the above-stated and reasons of record.

Information Disclosure Statement

5. The information disclosure statement filed April 1, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each

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publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

6. The rejection of claims 1-12 and 26-38 under 35 U.S.C. 112, first paragraph, is again maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-12, 26-33 and 39-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. of U.S. Patent No. 5,482,931 in view of Cassoni et al. Harris et al. teach of pharmaceutical compositions of peptides, inter alia oxytocin and their analogs and derivatives. In fact, Harris et al. teach of the preferred pharmaceutical peptide of carbetocin, (see column 2, lines 47-55). Harris et al. also teach that these pharmaceutical compositions contain various buffering agents, such as sodium acetate, (see column 2, lines 59-62). Moreover, Harris et al. teach of various modes of administration such as nasal, oral or parenteral administration, (see column 2, lines 15-20). Harris et al. further disclose of the use of a nasal spray of these pharmaceutical

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compositions for the management of diseases and abnormal conditions, (see column 3, lines 25-29). The prior art reference of Cassoni et al. teach of the administration of oxytocin and oxytocin analogues show receptor-mediated inhibitory effects on the proliferation of human breast carcinoma cells. Accordingly Cassoni et al. provide motivation for the treatment of breast cancer with oxytocin and its analogues, (see page 471, column 2, 4th paragraph). Clearly, one having ordinary skill in the art at the time of the invention would have been motivated to utilize the preferred pharmaceutical peptide of carbetocin as a treatment of breast cancer because carbetocin is an analogue of oxytocin.

9. Claims 13-25 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over Harris et al. of U.S. Patent No. 5,482,931 in view of Boer et al. Harris et al. teach of pharmaceutical compositions of peptides, inter alia oxytocin and their analogs and derivatives. In fact, Harris et al. teach of the preferred pharmaceutical peptide of carbetocin, (see column 2, lines 47-55). Harris et al. also teach that these pharmaceutical compositions contain various buffering agents, such as sodium acetate, (see column 2, lines 59-62). Moreover, Harris et al. teach of various modes of administration such as nasal, oral or parenteral administration, (see column 2, lines 15-20). Harris et al. further disclose of the use of a nasal spray of these pharmaceutical compositions for the management of diseases and abnormal conditions, (see column 3, lines 25-29). Leckman et al. teach of administering oxytocin to treat obsessive-compulsive disorder, (see abstract and pages 723 and 724). Due to the fact that Harris et al. specifically teach of the use of oxytocin and its derivatives and

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analogues, which includes carbetocin, to treat diseases and abnormal conditions, the skilled artisan would have been motivated to employ the oxytocin and its analogues and derivatives, which includes the preferred pharmaceutical peptide of carbetocin, to treat the diseases and abnormal conditions of the psychiatric disorder of obsessive compulsive disorder.

10. Claims 26- 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. of U.S. Patent No. 5,482,931. Harris et al. teach of pharmaceutical compositions of peptides, namely carbetocin, (see column 2, lines 47-55). Harris et al. also teach that these pharmaceutical compositions contain various buffering agents, such as sodium acetate, (see column 2, lines 59-62). Moreover, Harris et al. teach of various modes of administration such as nasal, oral or parenteral administration, (see column 2, lines 15-20). Harris et al. further disclose of the use of a nasal spray of these pharmaceutical compositions for the management of diseases and abnormal conditions, (see column 3, lines 25-29). The selection of a known material based on its suitability for its intended use, such as psychiatric disorders, supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

11. Claims 11, 12, 32, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. of U.S. Patent No. 5,482,931 in view of Cassoni et al. and in further view of Lipton et al. Harris et al. teach of pharmaceutical compositions of peptides, inter alia oxytocin and their analogs and derivatives. In fact, Harris et al. teach of the preferred pharmaceutical peptide of carbetocin, (see column 2, lines 47-55).

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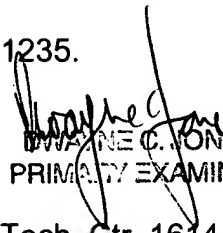
Harris et al. also teach that these pharmaceutical compositions contain various buffering agents, such as sodium acetate, (see column 2, lines 59-62). Moreover, Harris et al. teach of various modes of administration such as nasal, oral or parenteral administration, (see column 2, lines 15-20). Harris et al. further disclose of the use of a nasal spray of these pharmaceutical compositions for the management of diseases and abnormal conditions, (see column 3, lines 25-29). The prior art reference of Cassoni et al. teach of the administration of oxytocin and oxytocin analogues show receptor-mediated inhibitory effects on the proliferation of human breast carcinoma cells. Accordingly Cassoni et al. provide motivation for the treatment of breast cancer with oxytocin and its analogues, (see page 471, column 2, 4th paragraph). Lipton et al. disclose of the administration of tamoxifen or oestradiol to treat breast cancer. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be use for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art.”, *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


WAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
June 8, 2002